inventions. Claims 26 and 36-49 are under examination. Claims 26 and 39-46 are rejected under 35 U.S.C. §112, first paragraph, as allegedly not supported by an enabling disclosure. Claim 43 is rejected under 35 U.S.C. §102(b) as allegedly anticipated by Payelle et al. (1981). Claims 39-40 and 43-46 are rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Payelle et al. (1981) in view of Kundig et al. (1985).

This Response addresses each of the Examiner's rejections. Applicant respectfully submits that the present application is in condition for allowance. Favorable consideration of all pending claims is respectfully requested.

In the pending Office Action, the Examiner has made the Restriction Requirement Final. Claims 3-4, 14 and 29-38 are withdrawn from consideration as drawn to non-elected inventions.

It is respectfully submitted that claims 3-4, 14 and 29-38 have been canceled without prejudice by way of the instant amendment. Applicant reserves the right to pursue the subject matter of these canceled claims in one or more divisional applications.

It is further respectfully submitted that claims 39-40 have also been canceled without prejudice. Claims 41, 43-44 and 46 have been amended to delete the reference to claims 39-40. Claim 26 has been amended to further define the DNA used in transforming a semiallogeneic cell as genomic DNA from tumor cells. Claims 26 and 41-46 as presently amended are drawn to methods of preventing or treating cancer by administering to an animal an effective amount of a semi-allogeneic immunogenic cell, wherein said cell comprises an antigen-presenting cell expressing at least one class I MHC or class II MHC determinant that is syngeneic to said animal and at least one class I or class II MHC determinant that is allogeneic to said animal, and wherein said antigen-presenting cell is transformed with genomic DNA isolated from the tumor cells. Applicant reserves the right to pursue the subject matter encompassed by original claims 26 and 39-46 in a continuing application.

Claims 26 and 39-46 are rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not enabled by the specification.

The Examiner contends that, with respect to prevention of cancer, the specification provides no teaching or guidance as to how prevention of cancer in an animal species such as a human, can be achieved. Specifically, the Examiner contends that the specification does not teach how one skilled in the art would be able to ascertain that the subject was successfully protected against tumor or that the subject was never going to get the tumor at all. The Examiner argues that a demonstration of tumor antigen specificity *in vitro* alone cannot support the predictability of the method for prevention or treatment of tumor through administration of either a tumor cell antigen specific antibody or a T cell line expressing the appropriate idiotope. The Examiner further states that the establishment and growth of a tumor is subject to variables beyond antigen specificity. The ability of a host to suppress and thereby prevent the tumor from establishing itself will vary depending upon factors such as the condition of the host, the type of tumor and the tumor burden.

In the first instance, Applicant respectfully submits that claim 26 as presently amended characterizes the semiallogeneic antigen-presenting cell administered to a subject for the treatment and prevention of a cancer are transformed with genomic DNA isolated from the tumor cells.

Applicant submits that the presently claimed methods are fully supported by the instant disclosure. For example, the specification teaches the making of a fibroblast cell line of the H2-K^k MHC class I determinant transfected with a gene coding for H2-K^d MHC class I determinant, a DNA encoding IL-2, and genomic DNA from B16 (H2-K^k) tumor cells. The specification further teaches that, by administering such semi-allogeneic transfected cell to mice, the injection of B16 tumor cells fails to establish any tumor mass in the animals. See, e.g., pages 50-53 of the specification, and in particular, the paragraph bridging pages 50-51 and Figure 2; and the paragraph bridging page 51-52 and Figure 3. Clearly, semi-allogeneic

cells prepared in accordance with the present invention prevented the occurrence of a tumor in the subject animal. In addition, the specification teaches that semi-allogeneic cells prepared in accordance with the present invention also inhibited the growth of a pre-existing tumor in mice. See, e.g., pages 54-55 of the specification.

It is further submitted that, based on the specific examples related to animals such as mice, including the other general teachings provided in the specification, those skilled in the art would be able to successfully practice the claimed methods in animal species such as human, to prevent the occurrence or reoccurrence of a tumor, or to reduce or eliminate the growth of an existing tumor.

Accordingly, it is respectfully submitted that the presently claimed methods are fully supported by an enabling disclosure. Withdrawal of the rejection under 35 U.S.C. §112, first paragraph, is therefore respectfully requested.

Claim 43 is rejected under 35 U.S.C. §102(b) as allegedly anticipated by Payelle et al. (1981). Payelle et al. appears to teach the induction of protective T cells against a fibrosarcoma tumor (MCB6-1) by administering a hybrid cell made from fusing the fibrosarcoma (MCB6-1) to a fibroblast cell (A9). The hybrid cell appears to express both MHC class I and class II antigens.

It is respectfully submitted that claim 43 has been amended to delete the reference to claim 39 (relating to the use of hybrid fusion cells). Claim 43 as presently amended employs a semi-allogeneic cell which is transformed with genomic DNA isolated from tumor cells. It is observed that nowhere in the Payelle et al. reference is a method of preventing or treating tumors by using semi-allogeneic cells transformed with genomic DNA isolated from tumor cells disclosed. Therefore, Payelle et al. do not teach the claimed invention. As such, withdrawal of the rejection of claim 43 under 35 U.S.C. §102(b) is respectfully requested.

Claims 39-40 and 43-46 are rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Payelle et al. (1981) in view of Kundig et al. (1985).

The Examiner contends that Payelle et al. teach the induction of protective T cells against a fibrosarcoma tumor (MCB6-1) by administering a hybrid cell made from fusing the fibrosarcoma (MCB6-1) to a fibroblast cell (A9). The Examiner states that, although Payelle et al. do not specifically indicate that the fusion can be performed with any APC, Kundig et al. teach that fibroblasts are antigen presenting cells. The Examiner alleges that it is also clear to one of ordinary skill in the art that the conventional APCs (macrophages, as well as B cells and dendritic cells) would function similarly as the APC functions. Therefore, the Examiner concludes that it would have been obvious to one of ordinary skill in the art at the time of the invention to fuse a tumor cell with an antigen-presenting cell thereby producing a hybrid cell, which would evoke a therapeutic efficacy against the tumor cell.

It is respectfully submitted that the presently claimed methods employ a semi-allogeneic cell which is transformed with genomic DNA isolated from tumor cells. Neither the Payelle et al. reference nor the Kundig et al. reference teaches or suggests a method of preventing or treating tumors by using semi-allogeneic cells transformed with genomic DNA isolated from tumor cells. No recognition is provided in either reference as to the tumor-inhibiting effect of semi-allogeneic cells transformed with genomic DNA isolated from tumor cells. The teaching by Payelle et al. as it relates to the use of hybrid fusion cells is irrelevant to the invention as presently claimed.

Accordingly, the rejection of the claims under 35 U.S.C. §103(a) is overcome. Withdrawal of the rejection is therefore respectfully requested.

Attached hereto is a marked-up version of the changes made to the claims by the instant amendment. The attached page is captioned "**Version with Markings to Show Changes Made.**"

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

Please cancel claims 3-4, 16 and 29-40 without prejudice.

Please amend the remaining claims as follows:

26. (Twice Amended) A method of preventing or treating a tumor in an animal which comprises administering to said animal a tumor inhibiting effective amount of a semi-allogeneic immunogenic cell, wherein said cell comprises an antigen-presenting cell, expressing at least one class I MHC or class II MHC determinant that is syngeneic to said animal and at least one class I or class II MHC determinant that is allogeneic to said animal, and wherein said antigen-presenting cell is transformed with [and expresses] genomic DNA isolated from the tumor cells of said animal.

41. (Amended) The method according to [any of claims 26 or 39-40] claim 26, wherein said antigen presenting cell is further transformed with a nucleic acid molecule coding for at least one cytokine.

43. (Amended) The method according to [any of claims 26 or 39-40] claim 26, wherein said antigen-presenting cell is selected from the group consisting of a fibroblast, a macrophage, a B cell, and a dendritic cell.

44. (Amended) The method according to [any of claims 26 or 39-40] claim 26, wherein said tumor is a solid tumor or a hematological tumor.

46. (Amended) The method according to [any of claims 26 or 39-40] claim 26, wherein said animal is a human subject.

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